K102054

510(k) Summary

[Refer to 21 CFR 807.92]

DEC 2 2 2010

Owner:	Respironics California, Inc. 2271 Cosmos Court Carlsbad, CA 92011
Contact Person:	Tamatha Ley Regulatory Affairs Specialist Phone: (760) 918-1026 Fax: (760) 918-0169
Date Prepared:	November 8, 2010
Proprietary Name:	V200 Ventilator
Common Name:	Ventilator
Classification Name:	Continuous Ventilator (21 CR 868.5895, Product Code 73 CBK)

Predicate Devices:	**Manufacturer**	**Device Name**	**510(k) Number**
	Respironics California, Inc.	Esprit Ventilator	K981072

Intended Use of the Device:
The V200 Ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. It is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult, pediatric, and neonatal patients as prescribed by a physician. The ventilator is intended for use in either invasive or non-invasive applications.

The intended use is identical to that of the predicate the currently marketed Esprit Ventilator.

Device Description:
The V200 Ventilator is a hardware modification to the currently marketed Esprit that upgrades the look of the Esprit through minor changes to some of the external hardware components, as follows:

- The position of the encoder knob changed, as well as the attachment method
- Material changes were made to the top and bottom enclosure
- Dimensional, material, and attachment method changes were made to the bezel assembly
- The resins and color of the Heated Filter Assembly were changed
- Dimensional changes were made to the Overlay, as well as positioning of the hard keys, indicator lights, and icons

Ventilators with this updated look are sold under the brand name of the V200 Ventilator.

All electrical components, internal hardware components, firmware, and software are physically and functionally identical to those on the currently marketed Esprit Ventilator.

The V200 Ventilator technological characteristics with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, software, environmental specifications, and performance specifications are identical to that of the currently marketed Esprit Ventilator.

The V200 ventilator contains the identical software as the currently marketed Esprit Ventilator. The software options are enabled by downloading the operational software and installing the software option. They are integrated into the V200 Ventilator in the same manner as they are on the currently marketed Esprit Ventilator. The options can be installed either in the factory or in the field as an upgrade to existing V200 Ventilators.

All available options on the Esprit cleared subsequent to the original 510(k) (K981072) are also available on the V200 Ventilator. The table below identifies those options. Options that may be used in conjunction with each other are denoted by an 'X'. Options that may not be used together are denoted by "NA".

	Graphics	Respiratory Mechanics	Demand Flow	NICO-Esprit	Neonatal	Speaking Mode	Auto-Trak
SOFTWARE OPTIONS							
Graphics Option (K001208) Enhances the display screens with graphical data of the patient's flow, pressure, and volume.		X	X	X	X	X	X
Respiratory Mechanics (K023350) A diagnostic tool that provides the clinician the ability to measure and monitor a patient's respiratory condition while that patient is receiving ventilatory support. It consists for four maneuvers (Vital Capacity, Maximum Inspiratory Pressure, Occlusion Pressure at 100ms, & Static C&R) and calculates Dynamic C&R, Ti/Ttot, and Peak Lung Flow.	X		X	X	NA	NA	X
VCV Demand Flow (K034040) Provides additional flow/volume to patients when operator settings do not satisfy patient demand. It is available only in VCV mode for mandatory and assist breaths.	X	X		X	NA	X	X
NICO-Esprit Interface (K041412) Enables the ventilator to receive information from a NICO monitor and trend and display that information on the ventilator's User Interface	X	X	X		X	X	X
Neonatal Option (K051262) Provides support for intubated neonatal patients with an ideal body weight range from 0.5kg to 6.5kg	X	NA	NA	X		NA	NA

	Graphics	Respiratory Mechanics	Demand Flow	NICO-Esprit	Neonatal	Speaking Mode	Auto-Trak
Speaking Mode (K071212) Allows tracheostomized adult and pediatric patients who meet the assessment criteria to vocalize without the need of a speaking valve.	X	NA	X	X	NA		NA
Auto-Trak (K072450) Automatically adjusts I-Triggers and E-Cycles breathing without the need for user adjustment of I-Trigger and E-Cycle Thresholds under changing leak conditions.	X	X	X	X	NA	NA	
BREATH TYPES							
Volume Control Ventilation	X	X	X	X	NA	X	X
Pressure Control Ventilation	X	X	NA	X	X	X	X
Non-Invasive Positive Pressure Ventilation	X	NA	NA	X	NA	NA	X
VENTILATION MODES							
Assist/Control (A/C)	X	X	X	X	X	X	X
SIMV	X	X	X	X	X	X	X
CPAP	X	X	X	X	X	X	X
Spont/T	X	NA	NA	X	NA	NA	X
Spont	X	NA	NA	X	NA	NA	X
Apnea Backup	X	NA	X	X	X	NA	X
FEATURES							
Expiratory Hold (Auto-PEEP)	X	X	X	X	NA	NA	X
Positive End Expiratory Pressure (PEEP)	X	X	X	X	X	NA	X

Substantial Equivalence/Performance Testing:
The V200 Ventilator technological characteristics are identical to that of the currently marketed Esprit Ventilator with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, software, environmental specifications, and performance specifications.

This hardware modification has no affect on intended use, intended patient population, clinical benefit to the user or patient, operating principle, operating mechanism, operating algorithm, ventilation modes, functionality, features, or performance.

This submission contains comparative information and test data related to Electromagnetic Compatibility (EMC), Safety, and Shock and Vibration Testing to support the conclusion that the V200 Ventilator is substantially equivalent to currently marketed Esprit Ventilator.

These changes do not raise any new questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tamatha Ley
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DEC 22 2010

Re: K102054
Trade/Device Name: V200 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 14, 2010
Received: December 16, 2010

Dear Ms. Ley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102054

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Device Name: V200 Ventilator

Indications for Use:
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- Assist/Control (A/C)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Spontaneous (Spont)
- Spontaneous/Timed (Spont/T)
- Apnea (Backup Mode)

Prescription Use (Part 21 CFR 801, Subpart D)	X	AND/OR	Over-the-Counter Use (Part 21 CFR 807, Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102054